DEPARTMENT OF HEALTH & HUMAN SERVICES
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION

PHILADELPHIA DISTRICT

M23960

900 U.S. Customhouse
2nd and Chestnut Streets
Philadelphia, PA 19106

Telephone: 215-597-4390

WARNING LETTER

February 12, 1999

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. David A. Navazio, President
Gentell, Inc.
3600 Boundbrook Avenue
Trevose, Pennsylvania 19053

Dear Mr. Navazio:

From November 25, through December 18, 1998, and on January 26 and 28, 1999, Food and Drug Administration (FDA) Investigator Edward D. McDonald conducted two (2) inspections of your firm located at 3600 Boundbrook Avenue, Trevose, PA and determined that your firm manufactures and distributes wound care products used for the treatment of decubitus, venous and diabetic ulcers, post surgical wounds, and first and second degree burns. These products, Hydrogel Wound Dressing, Hydrogel Spray Gel for Wound Dressing, and Appligard Amorphous Hydrogel for Wound Care are devices as defined by Section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act).

The devices, Hydrogel Wound Dressing, Hydrogel Spray Gel for Wound Dressing, and Appligard Amorphous Hydrogel for Wound Care, are adulterated within the meaning of Section 501(f)(1)(B) of the Act, in that they are Class III medical devices under Section 513(f) and are required to have in effect approved applications for pre-market approval (PMA) pursuant to Section 515(a), or approved applications for investigational medical device exemption (IDE) under Section 520(g), and no such approvals or exemptions are in effect.

These devices are also misbranded under Section 502(o) of the Act, in that premarket notification submissions were not provided to the FDA as required by Section 510(k) and 21 CFR 807.81. Our inspection revealed that your firm has been manufacturing and marketing these device solutions since June 25, 1998 without filing the appropriate 510(k)'s.

Additionally, Hydrogel Wound Dressing is misbranded under Section 502(a) of the Act in that the labeling on the device and in your firm's catalogs contain statements which represent or suggest that the device is sterile. These representations or suggestions are false and misleading or otherwise contrary to fact, because the device is not sterile.

The inspections also revealed that the referenced medical devices are adulterated under Section 501(h) of the Act in that the methods used in, or the facilities or controls used for the manufacturing, packing, storage, or installation are not in conformance with the Quality System Regulation, as specified in Title 21, Code of Federal Regulations (CFR), Part 820, as follows:

> Hydrogel Saturated Gauze, Lot Nos., 000176008, 000203008, 00223008, 002230008, 0002239008, 000331008, labeled as sterile, have no sterility assurance in that the devices were not sterilized prior to distribution.
>
> There is no quality system in place to assure that Hydrogel Wound Dressing meets applicable requirements and specifications. For example, there is no device master record, device history record, sterile process validation, quality audits, and complaint system.
>
> During the January 1999 inspection it was determined this also applies to Hydrogel Spray Gel for Wound Dressing, and Appligard Amorphous Hydrogel for Wound Care.

We have taken note of your statements made during the initial inspection, and in your attorney's letter of January 25, 1999, and in your recall letter to your customers, where you expressed your intentions to recall all suspect lots of Hydrogel Wound Dressing and/or to cease manufacturing. However, when the Investigator returned to your firm on January 26, 1999 he found that 1000 devices previously stored at your facility were missing. You then reported to FDA that the 1000 devices were distributed to physicians, medical facilities and other users at trade shows.

This is not only counter-productive in your efforts to recall the product, and inconsistent with your stated intentions, it is an unacceptable practice because you have no assurance that the product will not be used on patients, and you did not maintain records of trade show distribution. Please advise us of your plans for recalled product and product presently in your warehouse.

This letter is not intended to be an all-inclusive list of deficiencies at your firm. As top management, it is your responsibility to ensure adherence to each requirement of the Act and its associated regulations. The specific violations noted in this letter and in the FDA-483 issued at the closeout of our inspection on December 18, 1998 (copy attached) are symptomatic of serious problems in your firm's manufacturing and quality assurance systems.

You should take prompt action to correct these violations. Failure to promptly correct these deviations may result in regulatory action being initiated by the FDA without further notice. These actions include, but are not limited to, seizure, injunction, and/or civil penalties.

Until the Quality System Regulation violations are corrected to FDA's satisfaction, and FDA has documentation to establish that such corrections have been made, export approval requests will not be granted. Additionally, Federal agencies will be advised of the Quality System deficiencies at your firm so that they may take this information into account when considering the award of contracts.

Please advise this office in writing within fifteen (15) days of receipt of this letter as to the specific actions you have taken or intend to take to correct the violations. If corrective action cannot be completed within fifteen working days, state the reason for the delay and the time within which the corrections will be completed.

Your reply should be directed to the attention of Richard C. Cherry, Compliance Officer, at the above address.

Sincerely yours,

Thomas D. Gardine

Thomas D. Gardine
District Director
Philadelphia District

Jci/rcc

Enclosures: Form FDA-483 dated 12/18/98

cc: PA Department of Health
132 Kline Plaza
Suite A
Harrisburg, PA 17104
Attention: Division of Primary Care & Home Health Services
Robert E. Bastian, Director